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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,289	05/15/2001	Nicholas J. Schork	G-055US04DIV	2959

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EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/858,289

Applicant(s)

SCHORK ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 31 and 48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed June 18, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. The withdrawal of claim 48 has been acknowledged.

RESPONSE TO ARGUMENT

3. Applicant argues that the cited difference in claims 31 and 48 does not lead to an undue search burden if claims 31 and 48 were examined together because said difference is directed not to the core of the method. Applicant's argument has been fully considered and found to be unpersuasive. It is noted that the limitation of "determining in unrelated individuals" is required in claim 48 but not required in claim 31 which causes claim 48 to be distinct from claim 31. Further, every limitation recited in the claims is search regardless whether Applicant considers said limitation to be "core" or not "core" of the claimed invention. Therefore, a search for the distinct inventions together as recited claims 31 and 48, respectively, would lead to an undue search burden due to their divergent subject matter.

4. Claim 31 is examined on the merits.

CLAIM REJECTIONS - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 31 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Macaubas et al. (June 1997).

7. This rejection is maintained with respect to claim 31, as recited in the previous office action mailed March 19, 2004.

RESPONSE TO ARGUMENT

8. Applicant argues that Macaubas et al. does not identify a plurality of biallelic markers in both the candidate genomic region and the plurality of random genomic regions utilized in determining the statistical significance in the differences of the association of the biallelic markers in these different genomic regions. Applicant's argument has been fully considered and found to be unpersuasive as discussed below.

9. It is noted that the instant claim 31 does not recite the limitation of "identify a plurality of biallelic markers in both the candidate genomic region and the plurality of random genomic regions utilized in determining the statistical significance in the differences of the association of the biallelic markers in these different genomic regions." Therefore, said limitation is not required in Macaubas et al. for anticipatory basis. However, claim 31 does recite "a method for determining whether a candidate genomic region harbors a gene associated with a detectable trait comprising determining whether the association...in a plurality of random genomic regions." The disclosure of Macaubas et al. cited below is consistent with the limitations of claim 31; therefore, the disclosure of Macaubas et al. anticipates the claimed invention. Further, Macaubas et al. discloses 15 DQB1 lineages (plurality of biallelic markers of candidate genomic region) associated with the DQ1 family show a C->A

nucleotide substitution in the fifteenth bases pair, resulting in a CAAA motif interrupting the CA repeat array (Table 1; Fig. 2). In contrast (different), allele sequences associated with non-DQ1 subfamilies showed an uninterrupted CA repeat motif (page 636, column 2, lines 14-22). Further, DQCAR alleles in non-DQ1 subtypes show high degree of size polymorphism (plurality of biallelic markers in random sequences) (Abstract etc.).

10. Applicant argues that Macaubas et al. fails to anticipate the claimed invention because it compares the variants of a microsatellite region already known to be associated with an HLA gene but not random genomic regions in different chromosomes. Further, Applicant argues that Macaubas et al. never refers to any “randomness” of the approach but to analyze in more than 2000 specific chromosome that were isolated from different populations. Due to the limitation “random” not being specifically defined in the instant specification, said limitation has been construed as broad as reasonable. Therefore, the disclosure of chromosome isolated from different populations of Macaubas et al. has been reasonably construed to be consistent with the limitation of “random” in claim 31.

11. Applicant argues that Macaubas et al. does not disclose any association between different allelic makers localizing a gene. “No polymorphism were actually measured simultaneously and compared indifferent DNA repetitive sequences for identifying a gene.” Applicant further argues that there is not any disclosure in which relates to associating a plurality of biallelic markers with various diseases. Applicant’s arguments have been fully considered and found to be unpersuasive because the limitations above recited in Applicant’s arguments are not recited in the instant claim 31. Therefore, said limitation is not required in Macaubas et al. for anticipatory basis.

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REJECTION RE-ITERATED

12. Macaubas et al. discloses a method of sequence analysis demonstrating that DQ1-associated DQCAR alleles have a single C -> A nucleotide substitution interrupting the CA repeat array (biallelic marker as defined in the specification, page 8, lines 25-29) (Abstract etc. and Table 1).

13. The detectable trait associated with said biallelic markers is HLA-DQ being expressed in the surface of cells in an immune response (page 635, column 2, last paragraph to page 636, column 1, lines 1-5).

14. The method of Macaubas et al. comprises the analysis of a DQB1*0201 is different from a plurality of biallelic markers corresponding to different chromosomes (random genomic regions) (Figure 1 and Table 1) resulting in different diseases (page 638, column 2, lines 1-10).

15. The above citations of Macaubas et al. anticipate the limitations of instant claim 31.

CONCLUSION

16. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

17. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. This application contains claim 48 drawn to an invention nonelected with traverse, filed July 02, 2003. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

19. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

20. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

21. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly

8/25/04

Ardin H. Marschel 8/30/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER